

NIOSH STATEMENT OF POLICY: CONFLICT OF INTEREST

DRAFT: 14 April 2006 -- 1000

1.0 PURPOSE

This document is a Statement of Policy¹ by the National Institute for Occupational Safety and Health (NIOSH) about potential or actual conflicts of interest² (COIs) of those persons or entities carrying out responsibilities for the NIOSH Dose Reconstruction Program (Program).

It is NIOSH's policy to require each employee of each entity covered by this Statement of Policy (as well as the entity itself) who performs any Program function as described in Sections 4.0 and 5.0 to undertake the following two actions: (1) to fully disclose all past, current or future anticipated employment-related, financial, supervisory or subordinate relationships that could pose a COI; and, if such a COI is found, (2) be excluded from performing a key Program function.

This Statement of Policy balances two competing values. First, NIOSH wants to ensure that it obtains all available factual information about radiation doses received by workers having potential benefits under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), from all relevant sources, including those individuals having any past or current employment-related, financial, professional or organizational relationships with the Department of Energy (DOE), an Atomic Weapons Employer (AWE), contract operators of DOE facilities, or with other parties having a stake in the general or particular outputs or outcomes of the Program. Second, NIOSH wants to ensure that all scientific judgments contained in key Program function documents that are made by NIOSH employees or its contractors' employees about dose reconstruction are free from potential or actual COIs.

This Statement of Policy sets forth principles that balance two competing values--complete gathering of all relevant information regardless of its source, concurrent with the development of dose reconstructions and site profiles of the highest scientific quality.

NIOSH's COI Policy is posted and will be updated on the NIOSH Web site at the following address: <<http://www.cdc.gov/niosh/ocas/TBD>>. NIOSH reserves the right to amend this Statement of Policy at any time of its choosing to take account of changed facts and circumstances.

2.0 COVERED ENTITIES

¹ This Statement of Policy is not intended to and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers, employees or any other person.

² The term "*conflict of interest*" means a conflict between the obligations of a person as a Program employee, or contractor, and a private interest and/or bias.

This Statement of Policy applies to all individuals, and their employers, who perform any function for the Program, including, but not limited to, those employed by NIOSH³ and those federal contractors performing Program functions.

3.0 DISCLOSURE AND EXCLUSION

Each individual performing any Program function as set forth in Sections 4.0 and 5.0 is required to disclose all potential or actual COIs by answering the questions set forth in Section 3.0. The existence of a COI excludes the individual with the COI from performing a key Program function⁴ (Section 4.0). The individual with the COI may, however, perform a non-key Program function (Section 5.0) involving the conflicted site or, in most cases, perform a key Program function involving another site.

3.1 Do you currently work for the U.S. Department of Energy (DOE)?

If yes, a COI exists and the individual with the COI cannot perform a key Program function for any site. If no, proceed to Question 3.2.

3.2 Do you, or did you, work⁵ at the DOE or Atomic Weapons Employer (AWE) site which is the subject of the document?

If yes, a COI exists and the individual with the COI cannot perform a key Program function for that site. If no, proceed to Question 3.3.

3.3 Do you, or did you, work for any of the past or current operators⁶ of the site which is the subject of the document?

If yes, then proceed to Question 3.4. If no, then proceed to Question 3.8.

3.4 Was your work for the operator only in the past?

³ The term "NIOSH" includes individuals working on Program-related duties in: the NIOSH Office of the Director (OD), the NIOSH Office of Compensation Analysis and Support (OCAS), the Department of Health and Human Services' (HHS) Office of the General Counsel (OGC), the Centers for Disease Control and Prevention's (CDC) Procurement and Grants Office (PGO) and Special Governmental Employees (Members of the Advisory Board on Radiation and Worker Health or ABRWH). For purposes of this Policy Statement, compliance by NIOSH itself is deemed to constitute compliance by these other federal entities subsumed within the term NIOSH.

⁴ The list of key Program functions in this Policy Statement is subject to revision by NIOSH at any time as facts and circumstances warrant. Key Program functions relate most directly to documents developed and used by the Program.

⁵ The term "work" means employment related to managerial, scientific or occupational safety or health matters for that operator and/or for that operator's subcontractors related to atomic weapons activities at the site.

⁶ The term "operator" includes employment related to managerial, scientific or occupational safety or health matters for that operator and/or for that operator's subcontractors at the site.

If yes, then proceed to answer Question 3.5. If no, a COI exists and the individual with the COI cannot perform a key Program function for that site.

3.5 During the time you worked for that operator, was that operator responsible for the site which is the subject of the document?

If yes, then proceed to Question 3.6. If no, then proceed to Question 3.8.

3.6 Does this time period overlap *at all* with the time period covered by the document?

If yes, then proceed to answer Question 3.7. If no, then proceed to Question 3.8.

3.7 Did your work for the operator have an impact⁷ on the site which is the subject of the document?

If yes, then a COI exists and the individual with the COI cannot perform a key Program function for that site. If no, then proceed to Question 3.8.

3.8 Did you work for DOE in the past?

If yes, then proceed to Question 3.9. If no, then proceed to Question 3.11.

3.9 Did your job duties at DOE include *substantial involvement*⁸ with the site which is the subject of the document?

If yes, then proceed to Question 3.10. If no, then proceed to Question 3.11.

3.10 Did your involvement overlap *at all* with the time period covered by the document?

If yes, then a COI exists and the individual with the COI cannot perform a key Program function for that site. If no, then proceed to Question 3.11.

3.11 Do you, or did you, have any financial, supervisory or subordinate relationship with DOE, the operator, any former DOE or operator employee, employee survivor, or attorney representing any of these parties?

⁷ The term "*impact*" means work that affected, modified or influenced any managerial, scientific or occupational safety and health matter at that site.

⁸ The term "*substantial involvement*" means personal participation in one or more managerial, scientific or occupational safety or health matters at or for the site.

If yes, then a COI exists and the individual with the COI cannot perform a key Program function for that site. If no, then no COI exists.

4.0 KEY PROGRAM FUNCTIONS

4.1 Dose Reconstructionist

A **Dose Reconstructionist** is responsible for conducting internal and external dose reconstructions for the Program, which include, but are not limited to: analyzing monitoring methods; performing uncertainty analyses; estimating organ or effective dose from available monitoring data; and incorporating any comments of the Dose Reconstruction Report Reviewer. A Dose Reconstructionist is responsible for any and all revisions to a Dose Reconstruction Report.

4.2 Site Profile Document Owner

A **Site Profile⁹ Document Owner** is responsible for coordinating and drafting all Site Profile Documents, ensuring all relevant information is captured in the document, evaluating the information, and establishing or setting forth specific findings or conclusions. The Site Profile Document Owner is the primary writer/editor of the Site Profile Document. The Site Profile Document Owner has an affirmative duty to seek out all relevant data and to objectively evaluate all relevant input with no special consideration given due to the source (site expert or subject expert).

All narrative or quantitative input to Site Profile Documents must be clearly attributed to each source(s) wherever it appears or is relied upon within a Site Profile document. In addition, both Site and Subject Experts shall be clearly identified on the approval page of every Site Profile Document to which they contributed.

A Site Profile Document Owner is responsible for any and all revisions to a Site Profile Document.

4.3 Special Exposure Cohort Petition Evaluation Document Owner

A **Special Exposure Cohort (SEC) Petition Evaluation Document Owner** is responsible for leading and documenting the evaluation of a qualified SEC petition to determine the feasibility of performing dose reconstruction. This individual is the primary writer/editor of the SEC Petition Evaluation Document. The SEC Petition Evaluation Document Owner has an affirmative duty to seek out all relevant data and to objectively evaluate input with no special consideration given due to the source (site expert or subject expert).

⁹ The term "site profile document" also includes any "Technical Basis Documents" or TBDs related to the site.

All narrative or quantitative input to SEC Petition Evaluation Documents must be clearly attributed to each source(s) wherever it appears or is relied upon within the SEC Petition Evaluation document. In addition, both Site and Subject Experts shall be clearly identified on the approval page of every SEC Petition Evaluation Document to which they contributed.

A SEC Petition Evaluation Document Owner is responsible for any and all revisions to a SEC Petition Evaluation.

4.4 Technical Information Bulletin Owner

A **Technical Information Bulletin Owner** is responsible for coordinating and drafting a Technical Information Bulletin which addresses a technical issue or concern regarding dose reconstructions for a specific exposure that may occur at one or more DOE or AWE facilities, ensuring that all relevant information is captured in the document, evaluating information, and establishing or setting forth a specific approach to resolve the technical issue or concern. The Technical Information Bulletin Owner is the primary writer/editor of the Technical Information Bulletin. The Technical Information Bulletin Owner has an affirmative duty to seek out all relevant data and information, and to objectively evaluate all relevant input with no special consideration given due to the source (site expert or subject expert).

All narrative or quantitative input to a Technical Information Bulletin must be clearly attributed to each source(s) wherever it appears or is relied upon within a Technical Information Bulletin. Each DOE or AWE site to which the Technical Information Bulletin applies must be listed in the Technical Information Bulletin. In addition, both Site and Subject Experts must be clearly identified on the approval page of every Technical Information Bulletin to which they contributed.

4.5 Reviewer of Key Program Function Documents

A **Reviewer of Key Program Function Documents** is responsible for conducting a scientific and technical review of the respective key Program function document (Dose Reconstruction Report, Site Profile Document, SEC Petition Evaluation, Technical Information Bulletin or any other document created for use by the Program). Anyone performing scientific and technical review at any level of any covered entity, including an ABRWH Member, is included in the definition of this review function.

4.6 Document Approval Authority

The **Document Approval Authority**, either a federal employee or an employee of a Program contractor, is responsible for exercising approval authority by signature to permit the use in the Program of a Dose Reconstruction Report, Site Profile Document, SEC Petition Evaluation, Technical Information Bulletin or any other document created for use by the Program. Any exercise of such approval authority is treated as a key

Program function under this policy, and the individual exercising that authority must ensure that the exclusions and attributions required by this Policy Statement have been met before signing the document and approving it for use in the Program. Anyone exercising Document Approval Authority at any level of any covered entity, including an ABRWH Member, is included in the definition of this function.

5.0 NON-KEY PROGRAM FUNCTIONS

5.1 Administrator

An **administrator** exercises managerial responsibility for specific aspects of the Program and may be either a federal employee or an employee of a Program contractor. All administrator-performed scientific and technical reviews of Dose Reconstruction Reports, Site Profile Documents, SEC Petition Evaluations and Technical Information Bulletins are considered key Program functions and are subject to COI exclusions.

5.2 Administrative Support Staffer

An **Administrative Support Staffer** provides administrative support for the NIOSH Dose Reconstruction Program and does not engage in any scientific or technical judgments regarding Dose Reconstruction, Site Profile Documents, SEC Petition Evaluation Documents or any other similar aspect of the Program.

5.3 Advisory Board on Radiation and Worker Health, Member

A **member of the Advisory Board on Radiation and Worker Health** (ABRWH) is an individual appointed by the President for a specific term, in order to advise the Secretary of HHS on scientific issues related to the Program. In addition to other duties, an ABRWH Member performs key Program functions, e.g., review of Dose Reconstruction Reports, Site Profile Documents and SEC Petition Evaluation Documents. When a ABRWH member has a COI and is called upon to perform one or more of these key Program functions, the following restrictions apply:

(1) *For the Dose Reconstruction Reports*, the ABRWH member with the COI may not serve as the member assigned to oversee the Dose Reconstruction in question, but may participate in deliberations and votes when considering roll-ups that include such a Dose Reconstruction;

(2) *For Site Profile Documents*, the ABWRH member with the COI may participate in related ABWRH deliberations, but may not vote or offer motions pertaining to the Site Profile Document; and

(3) *For Special Exposure Cohort Petition Evaluation Documents*, the ABWRH member with the COI may not take part in related ABWRH deliberations, votes or motions, but may offer comments as a member of the public during designated comment periods.

These greater restrictions for SEC Petition Evaluation documents relate to the document's increased specificity and finality.

5.4 Attorney

An **Attorney** is an employee of the HHS Office of the General Counsel and is responsible for ensuring the legal integrity of the Program; advising HHS, CDC, NIOSH and the ABRWH on legal matters concerning the Program, the EEOICPA and its regulations; and other related matters such as procedures for handling COIs.

5.5 Implementation Guide Owner

An **Implementation Guide Owner** is responsible for providing basic information on the general methods employed in reconstructing either internal or external doses; these guides acknowledge the claim-specific circumstances that may require a best estimate of dose, or for efficiency purposes an underestimate or an overestimate of the actual radiation dose received. The Implementation Guide Owner is the primary writer/editor of the Implementation Guide and is responsible for coordinating and drafting an Implementation Guide. The Implementation Guide Owner has an affirmative duty to seek out all relevant data and information, and to objectively evaluate all relevant input with no special consideration given due to the source (site expert or subject expert).

All narrative or quantitative input to an Implementation Guide must be clearly attributed¹⁰ to each source(s) wherever it appears or is relied upon within an Implementation Guide. By its nature, an Implementation Guide is relevant to all DOE or AWE sites.

5.6 Site Expert

A **Site Expert** is responsible for advising on site-specific issues and incidents as necessary for ensuring the completeness and accuracy of Site Profile Documents and Special Exposure Cohort Petition Evaluation Documents. Site experts are those individuals who, because of current or prior work experience (including consulting) at or for the site, possess or are aware of information that is relevant for reconstructing radiation doses experienced by claimants who worked at the site.

5.7 Subject Expert

A **Subject Expert** is responsible for advising on site-specific issues and incidents as necessary for ensuring the completeness and accuracy of Site Profile Documents and Special Exposure Cohort Petition Evaluation

¹⁰ The term "*attributed*" means the inclusion of footnotes, endnotes, a list of references, or other markings to identify the person, organization, or document sources for information in key Program function documents. The level of specificity of the attribution shall be appropriate to the importance of the information and may include, for example, document sections, paragraphs, tables or figures, or other key components of the document.

Documents. By contrast with Site Experts, Subject Experts are those individuals who have expertise in the subject matter of the activities performed at the site, but who do not have any current or prior work experience at or for the site itself.

6.0 COMPLIANCE

6.1 Procedures

All covered entities are required to demonstrate that they have put in place, and are complying with, internal procedures that contain requirements identical to those contained in this Statement of Policy. This shall be accomplished by each covered entity posting on its website, within sixty (60) days of final publication of this Statement of Policy on the NIOSH website, its own procedures demonstrating compliance with this Statement and compliance by any of its subcontractors. Updates of all the above-described procedures must also be promptly provided to the NIOSH Office of the Director (NIOSH OD) upon their issuance.

6.2 Disclosure

The appropriate Contract Officer for each covered entity performing work on the Program shall inform his/her employees of applicable COIs as described in this Statement, so that those employees may correctly complete and submit to a NIOSH-approved contractor entity Disclosure Form. This conflict information shall be updated by that Officer, and transmitted to the pertinent contractor employees, as needed. This Officer shall also ensure that such corporate COI disclosures are designated by the respective company to be made publicly available online by those entities.

6.3 Verification

Verification of federal employee and federal contractor COI disclosures shall be the responsibility of NIOSH and each federal contractor, respectively. To ensure greater compliance and accuracy, NIOSH will audit filed disclosure forms semiannually as a quality assurance measure. Any errors discovered shall be corrected immediately at the employer's or contractor's expense. Corrective actions may include, but are not limited to, transferring or removing workers found to have exclusionary conflicts, and redrafting and/or rereviewing documents as needed. Should a federal employer, federal contractor, federal employee, EEOICPA claimant, member of the general public or any other person wish to submit a complaint regarding a missing or erroneous disclosure, that party may do so by calling 1-800-35-NIOSH (1-800-356-4674).

6.4 Penalties

Failure by a contractor and/or its employee(s) to comply with these NIOSH disclosure and reporting requirements may result in removal of

employees or subcontractors from the Program, reduction in contract payments, and/or termination of contracts.

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